

WHAT IS CLAIMED:

1 1. A method for increasing likelihood of effectiveness of an ErbB antagonist
 2 cancer treatment, which method comprises administering a cancer treating dose of the ErbB
 3 antagonist to a subject, wherein an *erbB* gene in tumor cells in a tissue sample from the subject has
 4 been found to be amplified.

1 2. The method according to claim 1, wherein the ErbB is a HER2 protein.

1 3. The method according to claim 2, wherein the cancer is breast cancer.

1 4. The method according to claim 3, wherein the subject has been found to have
 2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1 5. The method according to claim 1, wherein the ErbB antagonist is an anti-ErbB
 2 antibody.

1 6. The method according to claim 5, wherein the ErbB is HER2, and the
 2 antibody is recombinant human monoclonal antibody (rhuMAb) 4D5.

1 7. The method according to claim 1 wherein the *erbB* gene amplification is
 2 detected by detecting fluorescence of a fluorescent-labeled nucleic acid probe hybridized to the gene.

8. The method according to claim 7, wherein the *erbB* gene is a *her2* gene..

9. The method according to claim 1, which further comprises administering a cancer treating dose of a chemotherapeutic drug.

10. The method according to claim 9, wherein the ErbB is HER2 and the chemotherapeutic drug is a taxoid.

11. The method according to claim 1 wherein the likelihood of effectiveness increases by about 30%.

12. A method for increasing likelihood of effectiveness of an anti-HER2 antibody to treat cancer, which method comprises administering a cancer treating dose of the anti-HER2 antibody to the subject, wherein a *her2* gene in tumor cells in a tissue sample from the subject have been found to be amplified.

13. The method according to claim 12, wherein the subject has been found to have a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

14. The method according to claim 12, which further comprises administering a cancer treating dose of a taxoid.

- 1 15. A pharmaceutical package comprising:
- 2 (a) a container comprising an ErbB antagonist for treating a cancer; and
- 3 (b) instructions to administer the ErbB antagonist to a subject if an *erbB* gene in
- 4 tumor cells in a tissue sample from the subject is amplified.

- 1 16. The package of claim 15, wherein the ErbB antagonist is an antibody.

- 1 17. The package of claim 16, wherein the antibody is an anti-HER2 antibody.

- 1 18. The package of claim 17, wherein the anti-HER2 antibody is rhuMAb 4D5
- 2 (Herceptin®).

- 1 19. The package of claim 15, wherein the instructions further comprise directions
- 2 to administer a chemotherapeutic drug in combination with the ErbB antagonist.

- 1 20. The package of claim 19, wherein the chemotherapeutic drug is a taxoid.

- 1 21. A method for identifying a patient disposed to respond favorably to an ErbB
- 2 antagonist for treating cancer, which method comprises detecting *erbB* gene amplification in tumor
- 3 cells in a tissue sample from the patient.

1 22. The method according to claim 21, wherein the subject has been found to have
2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1 23. The method according to claim 21, wherein the *erbB* is *her2*.

"PCT/US2004/010000"